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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,144	09/19/2003	Michael T. Carley	16497.1.1.5	7207
22913	7590	11/19/2007		
WORKMAN NYDEGGER 60 EAST SOUTH TEMPLE 1000 EAGLE GATE TOWER SALT LAKE CITY, UT 84111			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 11/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,144

Applicant(s)

CARLEY ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-22 and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7-5-07, 10-8-07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: W020/56227

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 2 August 2007.

Information Disclosure Statement

The information disclosure statement filed 8 October 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The foreign patents listed on pages 5-7 do not contain a copy of the patent document. Further, no copy was provided for the documents listed on pages 8-16, and they have not been considered. See 37 CFR 1.98(a)(2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

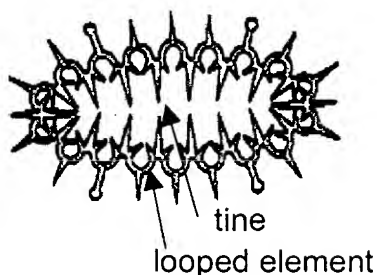
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17-20 and 36-41, 43-46, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence, et al. (US Patent 6,488,692).

Spence'692 discloses a clip having a ring-shaped body (MR) defining a plane and disposed about a central axis (intersection of lines B-B and MLA in Figure 7), the

body (MR) is capable of being moved from a substantially planar configuration to a transverse configuration because it is malleable (column 8, lines 16-23). Further, the body (MR) contains a plurality of loop elements (see alternate embodiment in Figure 9b) and a plurality of tines (see labeled copy of Figure 9b below) extending from the looped elements towards the central axis. Further, Spence'692 teaches spring elements (MD) that can be used to shape the clip (column 8, lines 25-30).



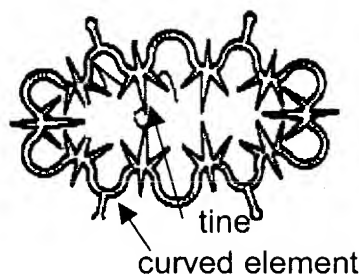
Regarding Claim 18, the spring element (MD) taught by Spence'692 is biased to move the tips of the tines into the relaxed state.

Regarding Claim 19, Spence'692 discloses the looped elements (see Figure above) is a series of outer curved regions connected to one another and the tines (see Figure above) extend from the connection regions of the adjacent curved regions.

Regarding Claims 20 and 36, Spence'692 discloses a clip having a ring-shaped body (MR) defining a plane and disposed about a central axis (intersection of lines B-B and MLA in Figure 7), the body (MR) is capable of being moved from a planar configuration to a transverse configuration because it is malleable (column 8, lines 16-23). Further, the body (MR) contains a plurality of curved elements (see alternate embodiment in Figure 9c) and a plurality of arcuate tines (see labeled copy of Figure 9c below and arcuate features in element TB in Figure 8a) extending from the looped

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elements towards the central axis. Further, as shown in Figure 8a, the tines are arcuate at the point that the tine extends from the ring. Further, Spence'692 teaches spring elements (MD) that can be used to resiliently move the tops of the tines away from each other (column 8, lines 25-30).



Claim 37, 38, 39: The plurality of tines contains primary tines and secondary tines having different lengths (see Figure 9b). The secondary tines are disposed on either side of the primary tines (see Figure 9b).

Claim 40: The body is biased towards the planar configuration for biasing the plurality of tines towards the central axis (column 8, lines 16-22).

Claim 41 and 46 and 48: The device disclosed by Spence'692 is formed of a unitary structure and is therefore capable of being formed from a unitary piece of material.

Claim 43: The spring element is capable of being expanded and compressed because it is made out of the same malleable material as the rest of the ring.

Claim 44 and 45: The body and spring element are biased towards the compressed state.

Claim 17, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Loshakove et al. (WO 00/56227).

Claim 17: Loshakove'227 discloses a generally annular-shaped device (300 in Figure 3a) in a plane, disposed about a central axis. The body is resiliently deformable towards a transverse configuration (Figure 3d and page 9, lines 28-30). The device also contains a plurality of tines (302) extending from looped elements (308) towards a central axis. The tines are parallel with the central axis in the transverse configuration (see Figure 3d). The device contains a spring element (310) between adjacent tines and looped elements for resilient movement.

Claim 41: The body can be formed of a single sheet of material since it is a unitary structure.

Claim 42: Loshakove'227 discloses the use of super elastic alloys (page 10, lines 31-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence'692, as applied to Claim 20, in further view of Gifford, et al. (US Patent 5,904,697).

Spence'692 teaches the limitations of Claim 21 and 22, except for a spiral orientation of the arcuate tines.

Gifford'697 teaches a clip with a spiral orientation of tines (499) (see Figure 40a, 40b) because the spiral configuration allows the clip to be interlocked with another clip. The length of the tines is longer than the perimeter of the body because this length is necessary for interlocking. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a spiral configuration because it allows the clip to be interlocked with another clip.

Claims 20, 36, 46, 47, 48 and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Loshakove'227 in view of Spence'692.

Loshakove'227 teaches a generally annular-shaped device (300 in Figure 3a) in a plane, disposed about a central axis. The body is resiliently deformable towards a transverse configuration (Figure 3d and page 9, lines 28-30). The device also contains a

plurality of tines (302) extending from looped elements (308) towards a central axis. The tines are parallel with the central axis in the transverse configuration (see Figure 3d). The device contains a spring element (310) between adjacent tines and looped elements for resilient movement. The body can be formed of a single sheet of material since it is a unitary structure. Loshakove'227 discloses the use of super elastic alloys (page 10, lines 31-33). Loshakove'227 does not teach arcuate tines.

Spence'692 teaches a device that contains arcuate tines (Figure 8a; see rejection for Claims 20 and 36 above regarding arcuate tines) because they are better able to engage with a bodily opening. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Loshakove with the arcuate tines taught by Spence in order to enhance the ability of the device to engage with the bodily opening around which it is placed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17-22 and 36-49 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 13-15, and 25-30 of copending Application No. 10/435,104. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: an annular shaped body containing tines, including primary and secondary tines.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17, 20, 36-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 3 and 16 of copending Application No. 11/028,133. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: an annular shaped body containing tines, including primary and secondary tines.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17-22, 36, and 41-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-3, 7-12, 13 and 14 of copending Application No. 11/344,891. Although the conflicting

claims are not identical, they are not patentably distinct from each other because are claiming common subject matter, as follows: an annular shaped body containing tines, including primary and secondary tines.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17-22, and 36-39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 8, 9, 11, 15 and 18 of copending Application No. 11/675,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: an annular shaped body containing tines, including primary and secondary tines.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17, 20, 36-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-11 of U.S. Patent No. 7,211,101. Although the conflicting claims are not identical, they are not patentably distinct from each other because are claiming common subject matter, as follows: an annular shaped body containing tines, including primary and secondary tines.

Response to Arguments

Applicant's arguments filed 2 August 2007 have been fully considered but they are not persuasive. Applicant argues that the device disclosed by Spence'692 is

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malleable, but not “resiliently deformable” because the ring is made of a material that has little shape memory that requires the surgeon to mechanically deform the ring in order to change its shape back to its original configuration. This argument is not persuasive because Applicant is arguing a limitation that is not claimed.

The term “resilience” according to Merriam-Webster’s Online Dictionary is defined as:

“the capability of a strained body to recover its size and shape after deformation caused especially by compressive stress”

Further, The American Heritage® Dictionary of the English Language: Fourth Edition. 2000. defines “resilient” as:

- “1. Marked by the ability to recover readily, as from misfortune.
2. Capable of returning to an original shape or position, as after having been compressed.”

Based on the definitions above, the term “resiliently deformable” does not inherently require that a material possess shape memory characteristics. The ring disclosed by Spence’692 is resiliently deformable because it is capable of recovering its original shape after its shape is changed by the user (column 8, lines 16-22).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Also, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8 October 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly,

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a) and MPEP § 609.04(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "MJ Hayes", with a long, sweeping horizontal stroke extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER